

Claims:

- 5 1. A stable oral composition comprising a therapeutically effective amount of desloratadine,
a stabilizer selected from a pharmaceutically acceptable organic compounds that provides
an alkaline pH, and pharmaceutically acceptable excipients.
- 10 2. A stable oral composition as claimed in claim 1, wherein said pharmaceutically
acceptable organic compound that provides an alkaline pH is selected from the group
consisting of
- primary, secondary, tertiary amines and cyclic amines;
- monosodium glutamate;
- polacrillin sodium;
15 - sodium alginate and
mixtures thereof.
- 20 3. A stable oral composition as claimed in claim 2, wherein said pharmaceutically
acceptable organic compound that provides an alkaline pH is meglumine.
- 25 4. A stable oral composition as claimed in claim 1, wherein said pharmaceutically
acceptable organic compound that provides an alkaline pH is used in an amount ranging
from about 0.01% to about 5% by weight of the composition.
- 30 5. A stable oral composition as claimed in claim 1, wherein the N-formyl impurity of
desloratadine is less than 0.5%w/w, when stored at 40°C and 75% relative humidity over
a period of 3 months.
6. A stable oral composition as claimed in claim 1, wherein the composition does not
undergo discoloration, when stored at 40°C and 75% relative humidity over a period of 3
months.

7. A stable oral composition as claimed in claim 1, further comprising an antioxidant.

5 8. A stable oral composition as claimed in claim 7, wherein said antioxidant is used in an amount ranging from about 0.01% to about 5% by weight of the composition.

9. A stable oral composition as claimed in claim 7, wherein said antioxidant is selected from the group consisting of butylated hydroxytoluene, butylated hydroxyanisole, DL-alpha-tocopherol, propyl gallate, octyl gallate, ethylenediamine tetraacetate, ascorbyl palmitate, 10 acetyl cysteine, ascorbic acid, sodium ascorbate, fumaric acid, lecithin and mixtures thereof.

10. A stable oral composition as claimed in claim 9, wherein said antioxidant is butylated hydroxy toluene.

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11. A stable oral composition as claimed in claim 7, wherein said stabilizer is a mixture of a pharmaceutically acceptable organic compound that provides an alkaline pH and an antioxidant, wherein the pharmaceutically acceptable organic compound that provides an alkaline pH is meglumine and antioxidant is butylated hydroxy toluene.

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12. A stable oral composition consisting essentially of a therapeutically effective amount of desloratadine, a stabilizer selected from a pharmaceutically acceptable organic compounds that provides an alkaline pH, and pharmaceutically acceptable excipients.